

# International project management in the pharmaceutical industry

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*Project management in a multicompany, multinational, multidiscipline environment with relatively small resources is considered. The impact of that environment and the methods to cope with it are examined, the experiences of a selected number of methods being reported. An attempt is made at providing a pathway for the synthesis of creativity and engineering leading to a minimal time span for completion of a project. The cost of slippage is discussed; along with a company's lost opportunities, slippages are considered to be the most detrimental project failures.*

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The drug development business, like many other development businesses, is based on calculated risks, research and innovation. It aims at optimizing the relation between available means and defined objectives. The resources, in terms of brains, creativity, manpower, technical equipment and clinical facilities, are available partly in the industry, but also in company-independent institutions such as hospitals and universities. Industry is seeking cooperation with and advice from these institutions, by offering to the outside partner practical research topics and participation in scientific and therapeutic progress. This is the overall objective of the drug development process: to attain scientific and therapeutic progress economically.

Project management plays its role within that frame-

work, among all the other sciences, techniques and disciplines necessary for achieving the overall objective.

This paper deals with a situation where project management is performed in a multicompany, multinational, multidiscipline environment, with relatively small resources. The multinational aspect adds the most variety to the task regarding drug registration requirements. Despite the efforts made in, for example, the Benelux countries, and quite recently in the European Free Trade Association (EFTA) group of countries, there are more differences than similarities, and a date for implementation of the regulations proposed by the EEC has not yet been fixed and may not be expected in the near future. Nevertheless, these tendencies to achieve a universal or regional consent must be acknowledged and supported, since they may help to simplify the present complex situation<sup>1</sup>.

The language problem should not be underestimated, nor should the attitude towards performing clinical trials, which, in Germany or France, differs from that in the USA or in other countries. Protocol for clinical trials, which may be appropriate for the conditions in USA, may not be suitable in the European countries, where adaptation to the local conditions is not only advisable, but necessary<sup>1</sup>. This has to be reflected in the development plan a company adopts.

There still remains a major difference to other industries: that is, the final testing of a project in its latest development steps is not in the hands of the industry. Rather, the clinical studies are in the hands of investigators, independent of the company. They may or may not follow the plans set up by the manufacturer's medical research group. Well-planned studies often are modified by clinicians, in a way that makes the results

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unacceptable for the drug regulatory agency. In other instances, however, reliable data is considered insufficient, because it has been obtained outside the given country, and repetition of studies is requested by national regulatory agencies for the sake of confirmation only<sup>2</sup>. Experience shows, however, that registration documentation with foreign data only, may take much longer for approval than documentation with some local contributions.

This is the environment in which drug development operates, and its project management has to meet this challenge.

## MANAGEMENT METHODS

It is important, for an international R&D operation, not only to keep track of present regulations valid in the countries it works in, but also to follow trends and to anticipate future developments in that field. The regulations for clinical trials and for registration vary from country to country, and the trends are sometimes convergent, sometimes divergent. It is necessary to have one or more people in an organization specifically to do the work of monitoring trends and regulations. Local personnel are needed to supply information regarding the local scene and culture; it is inefficient for people from outside a country to do clinical work there, not knowing perfectly the language and culture.

Looking at drug development as a process, it is necessary to optimize, in terms of economical use of resources and of time. Clearly, the methods offered by management science, business administration, industrial engineering and project management are applicable to the situation. In the manifold tasks performed under the name of R&D, one finds a wide variety of methods applied.

### Strategic business planning

Strategic planning includes research portfolio management and selection methods, long-range planning methods, forecasting methods for technological and commercial indicators, and project selection methods<sup>1-3</sup>. These methods help to bridge the gap between R&D activities and financial, marketing and general management.

### Operational management

For budgeting and cost control, accounting methods, performance measures, capacity measures and capacity-forecasting methods are used. Further, methods for planning and performing daily work efficiently are used, along with workshop management methods and organizational manuals, job descriptions, etc. These methods help to achieve an economical use of resources and to provide the required capacity for projects, at the right time and at low cost.

### Project management

Network planning methods (PERT, CPM, MPM, ABC, etc.), barcharts and check lists, when combined with group dynamical approaches, are efficient teamwork techniques (group moderation, TREND-analysis<sup>3</sup>, communication techniques). Project evaluation tech-

niques and project selection techniques and accounting methods (ROI, payback, DRR, DCF, NPV, . . .) help determine the expected future value of a project.

Since most accounting methods have been designed for achieving discrimination between 'good' and 'better' projects in a short run (1–5 years), they do not help assess the value of projects with a time horizon of 5–15 years to expected returns. In these cases, portfolio techniques may help<sup>4-6</sup>.

Further, one applies project documentation techniques, using word processing and EDP, leading to a hierarchy of project information carriers, each with a different degree of detail: starting with one line per project, progressing to one page per project, one brochure per project and ending with the full documentation, sometimes running to hundreds of thousands of pages<sup>3</sup>.

### Study management

Statistical methods (mathematical statistics and descriptive statistics) are used for planning and evaluating the studies; documentation techniques are used for study protocols, patient sheets and report generating; while stock management methods help overcome supply problems (clinical sample manufacturing and supply).

The different areas enumerated above by no means form a complete picture, but they illustrate the vast field of supportive effort needed to achieve an efficient drug development. This effort is a necessary prerequisite, but not the main purpose of the endeavours.

Looking at that list, one can conclude that the main problem is not the lack of appropriate and well elaborated methods, but their successful application. This requires that the middle and upper R&D management has a good working knowledge of those methods, and that a small staff (1–2 people) applies the methods on management's behalf. The level of knowledge necessary can be acquired in a few courses, requiring effort in addition to the usual effort needed to remain up to date in one's own scientific speciality.

## EXPERIENCE WITH THE METHODS

Experiences with some of the above mentioned methods are summarized in the following.

### Registration requirements

As a first insight into the international legal and practical requirements for testing and registration of drugs, the handbook of IFPMA<sup>7</sup> on this subject is of great help. However, it needs completion from a company-specific point of view (addresses, names, experts). On the whole, the better a company is able to comply with the local situation, the more efficiently it is able to handle its projects.

### Strategic business planning

The portfolio methods for assessing the status of present businesses and products, as described by the Boston Consulting Group, need extending. New products from R&D entering the market belong to the so-called group of stars, having been selected in the

belief that they have great potential for growth, market share, volume and profits. Therefore, within R&D, a tool is needed that will provide more differentiation regarding time horizon, chances for technical success and expected market success. Here, the R&D portfolio methods may play their role.

Experiences with research portfolio methods confirm the findings described in previous papers<sup>4-6</sup>. These methods help bridge the two time horizons: current business (finance, marketing, operations) with future business (R&D, new-product planning). Their use is connected with a minimal effort of 2-3 man-months per year, yielding many benefits for the organization.

### Operational management

There are many methods available; success depends on one's ability to properly use and not over-use them. Organizational manuals and job descriptions are of great help. They are established and updated periodically every 2-3 years, by the people doing the respective jobs and by their job neighbours, with the help of the respective supervisors. The time allocated to that task is kept very short so that it does not become unnecessarily sophisticated. The most important benefits to be drawn from that are as follows.

- Each person thinks through the tasks she/he is involved with, becomes aware of the possibilities for improvements, and clarifies what has to be done, how and why.
- Each cooperation with job neighbours is rediscussed.
- The roles are clarified for the next 1-3 years, and more efficient project work can occur because only the 'what' remains to be discussed and not the 'who' and 'how'.

### Project management

The authors use a commercially-available computerized network package (PROJACS, IBM), because the size of the operation does not require its own system. The benefits realized are:

- machine-made lists, networks and barcharts,
- short turn-around time for updating (half a day),
- end-user-adapted output (for most people, the lists and bargraphs are the best accepted outputs, whereas networks are for planners, project manager, R&D manager),
- cheaper than handmade lists and drawings.

Emphasis is placed on group dynamics and team work. Repeated training in efficient communication, group and meeting moderation has improved the capabilities of most of the project managers.

The selective use of word processing equipment for project documentation has increased the efficiency (or given savings) by a factor of between three and five. This improvement enables smaller operations to have available services which would be otherwise unachievable. This is particularly true for periodical progress reports or for continuously changing tables of content of project documentation, or reference lists. It is also valid for documents that are prepared over three or four draft stages before the final version is achieved.

### Study management

Systematization improves efficiency, but too much standardization is seen as red tape. The authors feel that there should be a core, which is common to all studies in all countries, and a flexible part that reflects the project's and the country's individualities. Here again, word processing equipment helps to provide adapted versions quickly. Attention has to be repeatedly drawn to the fact that the form helps achieve efficiency, and the content helps achieve the overall project objective.

All in all, the secret is not what method to use, but to make use of a good one in a systematical way. This requires discipline in work and in thinking on all hierarchical levels. Lack of discipline leads to sloppy work, loss of control and uneconomical use of scarce means.

### SYNTHESIS OF CREATIVITY AND ENGINEERING, DISCUSSION

The patient-oriented tasks of the research-based industry are seen as

- contributing to prophylaxis, diagnosis and therapy of diseases,
- producing and providing medicines and their optimal mode of application,
- (a complementary task) in cooperating in the creation and implementation of new disease management concepts<sup>8</sup>.

In that context, the project manager and his company internal and external partners have to develop the new drug. He has to win their interest, gain their cooperation and satisfy their sometimes conflicting goals. The project manager is the key person, who acts as an integrator: he brings each partner in the development enterprise to action, when his part is needed; he applies management methods to achieve an economical drug development; and he identifies the conflicts and brings them to solution or to a compromise.

In order to fulfil this task, we need both creativity and engineering, each at the appropriate time. Creativity does not end with the synthesis of the compound; it goes on through all development stages. In particular, it needs a major creative effort in clinical phases II and III, where the proper use of the new drug in therapy is established. As ever, imagination, observation and knowledge of biology and medicine are the ingredients for success.

There is also, in industry, a tendency to increase the bureaucracy, and the individual researcher is inclined to adopt a mentality that is directed towards compliance with duties rather than towards imaginative search for new leads and directions<sup>2</sup>.

There is also a point, however, where new ideas have to take a lesser role, and well-tried engineering methods be allowed to bring a project forward to its next goal. It is up to members and managers of project teams to watch continuously what is needed for the project at a given point in time.

Here, one can look also on the consequences of more or less efficient drug development: time is crucial; cost

of slippage is disastrous. A firm has a small number of new products, perhaps one every 1–3 years, or even less. New products are supposed to generate the basis for the future business and wealth. A successful product with large sales volume obviously changes the position of a company dramatically. The same product, some months or years later, might be worth considerably less, or even nothing. And even in cases where commercial success has not changed, sales volume lost during a slippage period may never be regained. Compared to the cost of lost opportunities, the cost of development is minimal. In the trade-off of time against money to be spent, time is more important.

Since no single country is representative of the whole world, one needs to establish country-specific development programmes and profiling studies, with a joint core of comprehensive well-documented claims and local amendments providing the fit to the local situation. The project manager has the task of finding out local peculiarities, and issues on which the majority agrees. His job is to integrate also on that level<sup>9</sup>.

Regarding the international view, Gross<sup>1</sup> says:

The example of a relatively small international community within Europe reveals the difficulties and problems, which have to be expected in the EEC or even more so in the Council of Europe. Even if each country were represented in a supranational organization by only two members, the size of the committee would exceed a membership, which can work efficiently, and it is easy to predict that matters will not become less difficult, but the whole procedure of drug acceptance is likely to become more tedious and slower than it is today.

This means that the time needed for activities within the companies has to be minimized.

## CONCLUSIONS

Many external factors and unfavourable outside influences may contribute to slippage, so much care is required to minimize their impact. However, if we manage better those parts under our own control, considerable improvement is made. This is not a question of a one-off action, rather it is a more difficult task requiring our continuous effort.

The chance of success of an enterprise or industry in the future depends largely on its ability to hold or expand its market positions. In stagnating or slowly growing economies, this is only possible with a detrimental effect on the less successful members of the market. Our ability to bring better qualified products and services to the market will be decisive. The following terms are specific to drug development project management.

- Select the compounds showing superiority in an item relevant to the patient and the doctor.
- Develop the compound in an internationally co-ordinated and cooperative effort.
- Pass the completed package of documents and certificates to the colleagues in marketing and production with timely forewarning, with complete information and with enthusiasm.

Success formulas are not recipes but concepts. In a recipe we read; 'one takes . . .'. A concept means that every one in a project team spontaneously, liberally and amply contributes with courage for the truth, with fortitude for the risks and with trust in oneself and in ones colleagues, respecting and understanding them.

Provided we keep the overall objective of our work regarding the patient and the treatment of diseases in mind while developing drugs we will provide a valuable service to medicine and to the industry in the long term.

It is our challenge to find solutions satisfying most of the competing goals in a minimal time span.

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